

REMARKS

Claims 1-14, 16-33, 35, 38 to 40, 71 to 97, 112 to 132 and 134-136 are pending in the application. Entry into the record is respectfully requested for newly added claims 137-147. Claims 15 and 89 have been cancelled. Claims 1, 8, 11-14, 16, 17, 19, 25, 26, 28, 31, 38, 71, 73, 79, 80, 84-86, 88, 90-92, 114, 115, 118 122, 125, 128-130, 132, 134-136 have been amended. The amendments are in part necessitated by the amendments to Claim 1 and 73. Support is found in the written examples and the claims as originally filed. The addition of claims 137-152 is not believed to cause an undue burden on the Examiner. These claims are already in the application for either the shell or linker. Applicants reserve their right to file continuation or divisional applications on all cancelled or deleted subject matter. No new matter is believed added.

Applicants also enclose herewith for completeness of the record, the Notice of Allowance for co-pending application 10/470,439 (Eudragit E100).

Rejection of Claims under 35 USC §103

The claims herein have three rejections as shown below:

I. Claims 1, 2, 7-16, 20-22, 39, 40, 73, 74, 81-84, 87-90, 92-95, 112 and 113 remain rejected under 35 USC §103(a) as being unpatentable over Petereit (US Pub. No. 2002/0160042) in view of Lehman et al, US 5,705,189 ('189).

II. Claims 3-6, 18 and 75-80 remain rejected under 35 USC §103(a) over Petereit in view of Bolles (US 3,779,942) and Zentner (US 4,795,644).

III. Rejection of Claims 1-33, 35, 38-40, 71-97, 112-132 and 134-136 remain rejected under 35 USC §103(a) over Petereit (US Pub. No. 2002/0160042), in view of Lehmann (US 5,705,189 ('189)), Hatano (US 6,309,666) and Klug et al. (US 3,314,809).

Applicants respectfully traverse all of these rejections. Applicants incorporate all their comments in their response of September 2009 in its entirety herewith.

In furtherance of the Examiner's comments on page 9 of the instant Office Action regarding modification of the claims in order to put them in condition for allowance, Claims 1 and 73 have been amended. In order to 1) "clarify the dissolution modifying excipients to include specific combinations", the claims have been amended to recite two specific combinations

(supported by the written Examples) wherein the first combination is that of a swellable solid and one of the other 4 DME's; as well as the other combination of a disintegrant and one of the other 4 DME's. The various combination of sugars/fillers/ and wicking agents will be placed in a continuation application.

For all the reasons as enumerated in Applicants earlier response, Petereit does not teach the combination of a swellable solid with a second dissolution modifying agent which is a disintegrant, a non-reducing sugar, a wicking agent, or a water soluble filler.

Petereit et al. also does not disclose nor suggest the specific combination of a disintegrant with a swellable solid; a non-reducing sugar; a wicking agent; or a water soluble filler. Thus, the subject matter of Claim 1 and 73 is believed to be novel and unobvious over the primary reference.

The claims also have been amended to "incorporate the above captured features of 1-4 into all independent claims".

Claim 1 and 73 have been amended to recite:

"wherein the extruded capsule shell composition is substantially pH-independent, and the capsule shell upon being exposed to a gastro-intestinal environment dissolves in a time/controlled release dependent manner."

The claims already include the pH –independent feature, and no include the time/controlled release dependent manner.

Applicants believe that the claims have been amended as suggested by the Examiner. If this is not the case, the Examiner is respectfully requested to contact the undersigned to discuss the matter further.

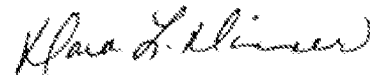
In view of these amendments and remarks, Applicants respectfully request withdrawal of each of the above identified rejections to the claims under 35 USC §103(a).

CONCLUSION

Reconsideration and withdrawal of the rejections based on 35 USC §103, and the prompt issuance of a Notice of Allowance, is respectfully requested. Should the Examiner have any questions or wish to discuss any aspect of this application, the Examiner is encouraged to call the undersigned attorney at the number below. If the Examiner does not find the claims allowable, Applicants respectfully request an interview with the Examiner at the earliest opportunity.

It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Dara L. Dinner".

Dara L. Dinner
Attorney for Applicants
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NOTICE OF ALLOWANCE AND FEE(S) DUE

20462 7590 03/24/2010

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 03/24/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/470,439

01/20/2004

Stephen Mark MacAllister

P51319

8632

TITLE OF INVENTION: PHARMACEUTICAL FORMULATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	06/24/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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P.O. Box 1450
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or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/470,439	01/20/2004	Stephen Mark MacAllister	P51319	8632

TITLE OF INVENTION: PHARMACEUTICAL FORMULATION

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	06/24/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
ROGERS, JAMES WILLIAM	1618	424-451000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 03/24/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/470,439	MACALLISTER ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant Arguments/Remarks Made in an Amendment filed 12/11/2009.
2. ☒ The allowed claim(s) is/are 47,48,50-61,129,130 and 132-137.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>09/09/2009</u> 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|--|--|

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

DETAILED ACTION

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dara Dinner on 3/11/2010.

The application has been amended as follows: claims 49,69-76,78-83,85,87-88,90-104,106,108-110,127-128,131 and 138-140 have been canceled.

Claim 47 has been amended as follows:

47. (currently amended) A process for making a pharmaceutical dosage form comprising the steps of:

a) introducing Aminoalkyl Methacrylate Copolymer E present in an amount of about 50 to 90% w/w and an excipient composition comprising at least one dissolution-modifying excipient which is polyethylene oxide present in an amount of about 5 to about 30% w/w; and optionally a second dissolution modifying excipient selected from the group consisting of

- i) a swellable solid present in an amount from about 5% to about 60% w/w;
- ii) a disintegrant present in an amount of about 5 to 50 % w/w;
- iii) a non-reducing sugar present in an amount of about 2.5 to 15% w/w;
- iv) a water soluble filler present in the amount of about 5 to 20% w/w;

Art Unit: 1618

v) a wicking agent present in the amount of about 2.5% to about 70% w/w;
vi) an inorganic salt present in an amount of 5 to 10% w/w; or a combination or mixture thereof;

and a lubricant present in an amount from 10 to about 25% w/w and optionally a plasticizer from about 0 to 5% w/w and/or a processing agent from about 0 to about 10% w/w; and/or a surfactant present in an amount of about 0.25 to 5% w/w; simultaneously into a first location of an elongated hot melt extruder, the first location having a temperature of about 50°C;

b) mixing said Aminoalkyl Methacrylate Copolymer E and said excipient composition in the hot melt extruder at a temperature ranging from about 50°C to about 125°C to form a homogeneous composition therein and substantially without thermal degradation of the Aminoalkyl Methacrylate Copolymer E and the excipient composition;

(c) extruding the homogeneous composition in the form of a strand from the hot melt extruder through a die at a second location distal from said first location, said second location having a temperature not greater than about 125°C;

c) cutting the strand into pellets; and

d) introducing said pellets into an injection molder and forming a thin-walled capsule shell compartments from said pellets by injection molding, and wherein the shell between and including the inner and outer surfaces of said shell is composed of the extruded and injection molded capsule shell composition.

In claim 48 line 3, the recitation of "croscarmellose sodium," has been deleted.

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In Claim 133 line 2, the recitation of "10 to 20" has been deleted and replaced with "5 to 30".

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618